

MICHAEL V. CHOBOTOV
Application No.: 10/029,584
Page 14

REMARKS

With entry of this amendment, claims 1, 3-10, 12-20, 22-29, 31-37, 62-64, 66, 68, 69, 71, and 74-95 are pending in the above-identified application. Claim 67 has been canceled without prejudice. In view of the remarks below, examination and reconsideration of all pending claims are respectfully requested.

Interview Summary

Applicants thank the Examiner for the teleconference of December 29, 2004, with Craig Wong (Reg. No. 45,231) and the undersigned, during which the present rejections to the claims under 35 U.S.C. § 103 were discussed. In particular, issues relating to an alleged motivation to combine the cited references were discussed. Applicants' remarks hereinbelow, in response to the Examiner's rejections under 35 U.S.C. § 103, serve to outline Applicants' arguments presented during the Interview. Per the Examiner's request, supporting citations to the references are also provided in the remarks. No agreement was reached during the Interview.

Claim Objections

The objection to claim 67 is obviated in view of the cancellation of claim 67.

Rejections under 35 U.S.C. § 103

Houser in view of McDermott

Claims 1, 3-5, 12-20, 22-24, 31-35, 69, 71, 74-77, 83-90, and 93-95 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Houser *et al.* (U.S. Patent No. 6,149,681, hereinafter "Houser") in view of McDermott *et al.* (U.S. Patent No. 6,312,462,

MICHAEL V. CHOBOTOV
Application No.: 10/029,584
Page 15

hereinafter "McDermott"). The Examiner contends that it would have been obvious to one of ordinary skill in the art to look to the teachings of McDermott to modify the vascular graft of Houser. The Examiner further alleges that "[w]hen the two-layered flap of flexible material is folded back to form a loop portion about the transversely oriented member ..., the flap will comprise a layer ... that is secured to itself and another layer" Applicants traverse the instant rejection for the reasons set forth below.

To establish a *prima facie* case of obviousness under 35 U.S.C. § 103, the Examiner must show, *inter alia*, a motivation or suggestion in the art to modify a reference or combine reference teachings so as to achieve the claimed invention. MPEP at §§ 2142 and 2143.01. The teaching or suggestion to make the claimed combination must be found in the prior art and cannot be based on applicant's disclosure. MPEP § 2142. *See also* MPEP § 2143, 2143.01 (citing cases). The Examiner cannot "simply reach conclusions based on [her] understanding or experience - or on [her] assessment of what would be basic knowledge or common sense." *In re Zurko*, 258 F.3d 1379, 59 U.S.P.Q.2d 1693, 1697 (Fed. Cir. 2001). Rather, the Examiner "must point to some concrete evidence in the record in support of these findings." Further, the cited art must be considered in its entirety, including portions that would teach away from the claimed invention. MPEP § 2141.02.

In the present case, as discussed during the Examiner Interview, there is no motivation to combine Houser and McDermott to achieve the claimed invention. Houser discloses a graft that achieves an effective seal and fixation within a vessel without additional sealing or fixation means. (See Houser at, e.g., col. 2, lines 33-35, stating that an object of the graft disclosed therein "is to provide a more effective fixation ... within a body lumen, and ... a more effective seal against leakage" (emphasis provided).) The graft has a structural layer, "formed of a resilient body compatible metal or polymer," and a graft material layer disposed over and secured to the structural layer. (Houser at Abstract.) The structural layer acts as a stent. When released at a site within a vessel, the structural layer radially enlarges to achieve

"intimate contact" of the graft within the vessel wall, fixing the graft at the site "without hooks or other auxiliary fixing devices." (Houser at col. 4, lines 32-37.)

In contrast, McDermott teaches that the injection of a fluid between the walls of PTFE expands the device and locks the device into place. (*See* col. 3, lines 6-27). Moreover, McDermott appears to teach against the inclusion of a stent in its graft. In particular, at col. 5, line 67 to col. 6, line 4, McDermott states the following:

However, as noted above, inclusion of a stent in a graft significantly increases the profile of the graft in its compressed state. With the current invention, the graft lacks a permanent stent so that it can be maximally compressed.

[Emphasis provided. *See also* col. 3, lines 60-65 (stating that the principle of the invention is to provide "a stent-free prosthesis").]

While it may be possible to combine Houser with McDermott, there must be some suggestion of the combination. *See* MPEP § 2143.01 (stating that "[t]he mere fact that reference can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination".) Because Houser describes a graft that achieves an effective seal and fixation within a vessel without auxiliary means, and McDermott describes using the inflatable channels as fixation means without the use of a stent, the skilled artisan reading the references would not look to the teachings of McDermott to modify the graft of Houser. Further, since McDermott is explicitly desirous of minimizing the profile of the graft and states that the graft lacks a stent for maximal compression, McDermott teaches away from the inclusion of a stent to the graft.

Moreover, as noted in the Interview, even assuming *arguendo*, a motivation to combine Houser and McDermott in the first instance, there is still no particular motivation or suggestion in the cited art to use both layers of McDermott's graft (which are separate except for connections at distinct circumferential regions, *see, e.g.*, Figs. 3 & 4) for forming the flap of

Houser. This is especially the case since (a) as disclosed by Houser, a single layer is sufficient to secure the graft material layer to the rectangular frame and (b) forming the flap as proposed by the Examiner, with both layers of graft material, would further increase the delivery profile of the graft, contrary to the teachings of McDermott.

In view of the above, withdrawal of the instant rejection of claims under 35 U.S.C. § 103 is respectfully requested.

Layne in view of McDermott

Claims 62, 64, 66, 67, and 91 stand rejected under 35 U.S.C. § 103 as allegedly unpatentable over Layne (U.S. Patent No. 6,558,414) in view of McDermott. The Examiner contends that it would have been obvious to one of ordinary skill in the art to look to the teachings of McDermott to modify the vascular graft of Layne. The Examiner further alleges that "[w]hen the two-layered flap of flexible material is folded back to form a loop portion about the serpentine expandable member ..., the flap will comprise a layer ... that is secured to itself and another layer" Applicants traverse the instant rejection.

As noted in the Examiner Interview, there is no motivation to combine Layne and McDermott to achieve the claimed invention. First, McDermott teaches away from the proposed combination. Layne discloses graft formed of a series of stents partially encapsulated in PTFE. As discussed above in Applicants' response to the Examiner's rejections in view of Houser and McDermott, McDermott teaches against the inclusion of a stent in its graft. McDermott states that "inclusion of a stent in a graft significantly increases the profile of the graft in its compressed state" and that "[w]ith the current invention, the graft lacks a permanent stent so that it can be maximally compressed." (McDermott at col. 5, line 67 to col. 6, line 4 (emphasis provided).)

Moreover, again as discussed in the Interview, the Examiner's proposed combination of Layne's stent-encapsulated strips of woven PTFE (*see* Layne at Fig.2) with McDermott's double-walled structure would appear to prevent McDermott from forming its inflatable circumferential channels. *See* MPEP § 2143.01 (a proposed modification cannot render the cited art unsatisfactory for its intended purpose).

In view of the above, withdrawal of the instant rejection of claims under 35 U.S.C. § 103 is respectfully requested.

Layne in view of McDermott and Lombardi

Claim 63 stands rejected under 35 U.S.C. § 103 as allegedly unpatentable over Layne and McDermott as applied to claim 62 and in further view of Lombardi (WO 01/58384 A1).

Applicants respectfully traverse the instant rejection. Claim 62, from which claims 63 depends, is non-obvious for the reasons set forth above in response to the Examiner's rejections in view of Layne and McDermott. Therefore, claim 63 is allowable over Layne, McDermott, and Lombardi at least for the reasons that claim 62 is allowable. Withdrawal of the instant rejection is respectfully requested.

Houser in view of McDermott and Edwin

Claim 6, 25, 37, and 78 stand rejected under 35 U.S.C. § 103 as allegedly unpatentable over Houser and McDermott as previously applied to claims 5, 24, 35, and in further view of Edwin *et al.* (U.S. Patent No. 6,245,099).

Applicants respectfully traverse the instant rejection. Claims 5, 24, 35, and 77, from which claims 6, 25, 37, and 78 respectively depend, are non-obvious for the reasons set

forth above in response to the Examiner's rejections in view of Houser and McDermott. Therefore, claims 6, 25, 37, and 78 are allowable over Houser, McDermott, and Edwin at least for the reasons that claims 5, 24, 35, and 77 are allowable. Withdrawal of the instant rejection is respectfully requested.

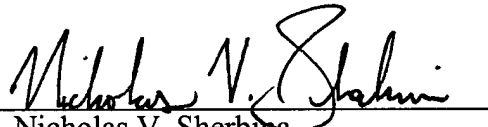
CONCLUSION

Applicants respectfully request reexamination and reconsideration of the claims in this matter. If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 206-467-9600.

Respectfully submitted,

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By: _____


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